Trinity Health

June 9, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1785-P; Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership

Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1785-P. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 123,000 colleagues and more than 26,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 135 continuing care locations, the second largest PACE program in the country, 136 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 1,324 primary care providers and 4,193 specialty care providers. Based in Livonia, Michigan, its annual operating revenue is $21.5 billion with $1.4 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 2 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participated in the “enhanced track”, which qualifies as an advanced alternative payment model (AAPM). Two of the 14 markets also participate in CPC+. In addition, we have participated since 2014 in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Hospital Financials and Market Basket update

Given the extraordinary inflationary environment and continued labor and supply cost pressures hospitals face, Trinity Health is deeply concerned with the proposed net operating payment increase of 2.8% in the FY24 IPPS rule. This woefully inadequate update will result in the fourth consecutive year where the IPPS payment update is not reflective of the actual cost increases hospitals are experiencing. This update, as well as the payment updates for FYs 2021, 2022, and 2023, does not capture the unprecedented increase in the cost of caring for patients and comes at a time when many non-profit health systems are struggling to stay afloat after years of COVID-related financial losses, high inflation, and increased labor expenditures.

CMS finalized market basket updates of 2.4 percent, 2.7 percent and 4.1 percent for FYs 2021, 2022 and 2023 respectively. According to CMS' latest forecasts, these updates are notably lower than what CMS is now estimating based on actual data. Of particular note, CMS now estimates that total hospital costs increased by 5.7 percent in FY 2022, which is *3 percentage points higher* than the market basket update that CMS finalized for that year (2.7 percent).[1] This underpayment is one factor leading to significant financial challenges for Trinity Health and other health systems.

We urge CMS to:

- **Use its special exceptions and adjustment authority to make a one-time retrospective adjustment of 10-15% to the market basket to account for what hospitals should have received in 2022 when accounting for inflation.**
- **Establish a threshold whereby if the payment differential between what was provided and actual costs is greater than 1.5 percentage points, CMS would retroactively adjust payments for that year.**
- **Rebase the market baskets more frequently and at least every three years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.**

The cost of caring for patients in recent years has been significantly higher than the increase reflected in the Medicare annual payment updates. Since 2019, Medicare rates have increased 6% while Trinity Health's cost per case has increased 14% including:

- 15% increase in labor costs.
- 17% increase in supply costs.
- 24% increase in drug costs.
- 10% increase in implant costs.

In addition, the average hospital length of stay has increased nationally by 19%[2]. To maintain access to quality care for Medicare beneficiaries, reimbursement must cover the cost of delivering care. At Trinity Health, 41% of revenue comes from Medicare. Unfortunately, as noted above, Medicare payment rates have not kept up with the increased costs of delivering care across all settings. With 18% of our revenue also coming from Medicaid and patients who are uninsured, there is little room to cost-shift Medicare losses to other payers. Consequently, not-for-profit health systems, like Trinity Health, are struggling to keep service lines open to care for our communities.

---

[1] CMS Market Basket history and forecasts, https://www.cms.gov/files/zip/market-basket-history-and-forecasts.zip

[2] Issue-Brief-Patients-and-Providers-Faced-with-Increasing-Delays-in-Timely-Discharges.pdf (aha.org)

In recent years, the data sources used for developing annual payment updates have not accounted for the impact of inflation, nor have they captured the staggering increase in labor costs, including contract labor, which hospitals have experienced since the start of the COVID-19 pandemic. These costs are significant— Trinity Health spent nearly $770 million in FY22 on contract labor, a 298% increase from pre-pandemic spend.
The proposed update to the hospital market basket of 3.0 percent for FY 2024 is based in part on its projection of a 3.9 percent increase in compensation and benefits for FY 2024. CMS updates labor costs using data from the U.S. Bureau of Labor Statistics' (BLS) Employment Cost Index (ECI). Specifically, CMS uses a four-quarter rolling average of change in compensation and benefits as measured through the ECI survey of hospital workers. There is a lag in the data that CMS uses to update the market basket annually, and the proposed update is based on historical data through third quarter of CY 2022.

The use of contract labor and overall increased labor costs have been driven by significant workforce shortages. Before the pandemic, many clinical staff were in short supply and growing closer to retirement age. According to pre-pandemic research published in 2018, healthcare was projected to be short more than 1 million nurses by 2020 as a result of nurse retirements, an aging U.S. population and a stagnant talent pipeline. Since that time, the pandemic has only exacerbated matters, prompting a significant increase in clinician resignations and retirements; for example, more than 500,0000 nurse retirements were expected in 2022. A recent analysis finds that by 2025, it is expected that the United States may have a gap of between 200,000 to 450,000 nurses available for direct patient care, equating to a 10 to 20 percent gap.

This significant and growing deficit in the workforce supply indicates that it is unlikely these increased labor costs are transitory, but rather a new normal that reflects shifting market dynamics. As talent shortages become more severe, providers are paying more to attract and retain scarce staff, and our analysis indicates it is likely that these wage increases have set a new floor. However, the BLS' ECI does not accurately reflect the increased and persistent labor costs resulting from these projected ongoing shortages.

Additionally, the productivity update included in the proposed rule assumes hospitals can replicate the general economy's productivity gains. However, in reality the critical financial pressures that hospitals and health systems continue to face have resulted in productivity declines, not gains.

Rate Setting
CMS proposes to return to usual methodologies of using most recently available data without adjusting for COVID anomalies.

Trinity Health supports returning to usual methodologies.

Medicare DSH
CMS estimates $6.71 billion in available uncompensated care, a decrease of $164 million from, the main driver of which are estimates in hospital discharges.

Trinity Health is concerned that the proposed uninsured estimate does not fully account for the end of PHE and the expiration of certain provisions, including continuous Medicaid eligibility, which will likely increase the rate of uninsured. CMS acknowledges an anticipated 11% reduction in Medicaid enrollment; however, several studies have highlighted that the end of this policy will likely cause a spike in uninsured and would be higher than what CMS is predicting. According to an Urban Institute study, more than 14 million people

could lose Medicaid coverage and we have already seen reports that the unwinding is going much worse than expected.[3] While some of these individuals could be eligible for other coverage, such as through the Marketplace, several factors (including state policies) could impact whether individuals receive alternative coverage. A Kaiser Family Foundation analysis found that among individuals disenrolling from Medicaid, 65 percent had a period of uninsurance in the year following disenrollment and only 26 percent enrolled in another source of coverage following the year of disenrollment.

Because of the end of the continuous enrollment provision, Trinity Health is skeptical that the uninsured rate will remain level from FY 2023 to FY 2024. **Therefore, we urge CMS to re-evaluate assumptions regarding uninsured (for Factor 2) in light of the expiration of certain COVID-19 PHE provisions when updating its estimate of uninsured in the final rule. At a minimum, CMS should provide additional detail on how it accounted for the expiration of this policy in its analysis.**

In addition, DSH is calculated only off of inpatient volume. As location of care is changing, there is a significant amount of uncompensated care that isn't accounted for. **CMS should engage stakeholders and consider ways to capture uncompensated care provided in non-acute settings.**

Uncompensated Care Distributions

CMS proposes to continue the three most recent years of audited cost reports to calculate the uncompensated distribution. For FY24 CMS would use discharge data from 2019, 2021, and 2022.

Trinity Health continues to support this policy, as it aligns with recommendations we have made in previous comments. Using a three-year average mitigates the impact of significant swings from year to year and helps ensure predictability for CMS rate setting and provider budget planning. In addition, we support not including data from 2020 as it would have likely underestimated the number of discharges due to the lower utilization experienced during COVID.

Urban to Rural Reclassifications for Capital DSH

Under the capital IPPS, only urban hospitals with 100 or more beds are eligible for capital DSH payments.57 Section 1886(d)(8)(E)(i) of the Act indicates that when a hospital reclassifies from urban to rural, it is treated as rural for all IPPS operating payment purposes. Since October 1, 2006, CMS has been treating an urban to rural reclassified hospital as rural for capital DSH payments—e.g., ineligible to receive them.

On September 30, 2021, in Toledo Hospital v. Becerra, the U.S. District Court for the District of Columbia found that CMS's policy of not providing capital DSH payments to urban hospitals that are reclassified as rural was arbitrary and capricious. The court concluded, the record did not demonstrate that CMS took relative costs into account when considering the rule and the policy at issue. **In response to the court's ruling, CMS is proposing that effective for discharges occurring on or after October 1, 2023, hospitals reclassified as rural will no longer be considered rural for purposes of determining eligibility for capital DSH payments. Trinity Health supports codifying this policy.**

[3] Buettgens, Matthew and Jessica Banthin, "Estimating Health Coverage in 2023," Urban Institute, May 10, 2022, https://www.urban.org/research/publication/estimating-health-coverage-2023

COVID-19 Add-on Payment

Trinity Health urges CMS to work with Congress to maintain the COVID-19 DRG add-on payment for inpatient admissions and analyze data to determine what the appropriate payment should be for a permanent DRG.

Reasonable Cost Payments for Nursing and Allied Health Education (NAHE)

Medicare inadvertently overpaid NAHE reasonable cost payments associated with Medicare Advantage (MA) beneficiaries from FY 2012 through FY 2019. The Consolidated Appropriations Act (CAA), 2023 prohibited CMS from recouping those overpayments.

Trinity Health supports the policy outlined in the rule, which would protect NAHE and fully implement the TRAIN Act passed by Congress last year. As drafted, the proposed rule would return all of the funds recouped from hospital-based schools of nursing and allied health.

Wage Index

Low wage index policy

CMS proposes to continue its policy to increase wage index values for low-wage index hospitals. For hospitals with a wage index value below the 25th percentile, the agency would increase the hospital's wage index in a budget neutral manner by adjusting the national standardized amount for all hospitals.

The low-wage index policy was intended to only be in place for four years to allow enough time for increased wages to be reflected in cost report data, and thus was set to expire after FY 2023. However, CMS notes that it only has one year of data under the policy because of the lag in applying cost report data to the wage index.

The low-wage index policy has been subject to on ongoing litigation (Bridgeport Hospital vs. Becerra), with the D.C. District Court ruling last spring that the Secretary did not have the authority under statute to adopt the low-wage index policy and ordering additional briefing on the appropriate remedy. CMS subsequently appealed the court decision, and that appeal is still pending.

Trinity Health recognizes the need for policies to help support rural hospitals and the communities they serve; however, we continue to not support this policy. We urge HHS and Congress to develop a comprehensive, long-term approach to help these facilities. As disparities among geographic regions and challenges faced by rural hospitals continue to grow, **HHS should work with Congress to provide funding for low-wage hospitals that is not subject to budget neutrality.**

Trinity Health continues to support establishing a permanent 5% floor on wage index decreases to reduce volatility in the wage index.

Rural Floor calculation

CMS will continue to include urban and rural reclassified hospitals in the rural floor wage index. CMS is also proposing to treat a hospital that reclassifies to a rural area as the same as a hospital that is physically located in a rural area.

Trinity Health strongly supports this proposal and urges CMS to finalize.

Health Equity

If finalized, CMS would change the severity designation of the three ICD-10-CM diagnosis codes describing homelessness (Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02

(Unsheltered homelessness)) from non-complication or comorbidity (NonCC) to complication or comorbidity (CC) for FY 2024. CMS bases this proposal on its analysis of claims for which these codes are listed as a secondary diagnosis, which resulted in a finding that the resources involved in caring for a patient experiencing homelessness are more aligned with a CC severity level than NonCC.

Among the factors that may cause increased financial impact to hospitals, CMS notes that patients experiencing homelessness can require longer inpatient stays due to needing a higher level of care and/or difficulty finding discharge destinations to meet these patients' needs.

Trinity Health strongly supports health equity. We see this policy as a watershed moment as it's the first time CMS will be linking payment for social influencers of health to payment in traditional Medicare. Trinity Health supports this change and urges CMS to finalize this policy as resource utilization for this population is more aligned with CC than NonCC. Homelessness increases the length of stay for the patient and makes discharge planning more difficult, thereby increasing the amount of resources used per case. The new policy would improve reimbursement for treating this population and prompt better collection of meaningful data. **Trinity Health urges CMS to evaluate the severity designation for additional Z codes to in the future.**

Ownership Disclosure
In line with what is currently required for safety net care facilities (SNFs), CMS proposes to expand the requirement of ownership disclosure to all facilities that complete the form CMS-855A.

Trinity Health supports reporting that would make facility ownership transparent.

Rural Emergency Hospitals (REH)
Reimbursement
The Consolidated Appropriations Act of 2921 established a new provider type—Rural Emergency Hospitals—effective CY2023. CMS proposed several policies related to REH in the FY24 IPPS rule, including: codifying enrollment requirements, updating definitions in survey and certification regulations, adding a requirement that state agencies must report any EMTALA violations by REHs to CMS, and allowing hospitals to count resident training time in REHs for GME purposes.

Trinity Health appreciates the continued work on the REH designation. We've identified a significant gap in the lump/facility payment amount in the REH regulations in that they omit Medicare Advantage volumes in the calculation and account only for traditional Medicare. Our analysis of the current Medicare Advantage (MA) reimbursement requirements is that they are to follow CMS reimbursement, thus an REH will only receive the OPPS +5% for this outpatient volume. This creates a gap in the facility payment for the MA patients that the CAH would have received historically from the cost based interim payment. **Trinity Health urges CMS to address this issue in the original facility payment calculation as it is not included in any other reimbursement.**

340B Eligibility
Trinity Health urges CMS to update the 340B eligible provider list to include the REH provider designation. Trinity Health relies on the 340B drug savings program to help provide key services to the low-income and rural patients we serve. The 340B program is a vital lifeline for safety-net providers, supporting critical health services in our communities including a broad range of services that expand access to medications, medical treatments, primary care and specialty care for those who are poor and vulnerable.

REH are now an established provider type under CMS guidelines and the COPs are very similar to those of critical access hospitals (CAH) and the populations REHs serve are reflective of the CAH rural community. Rural providers that will convert to the REH designation also own and operate Rural Health Clinics and other critical outpatient services to ensure access to care in their communities. Thus, REHs should be 340B eligible providers.

GME payments to REH
To increase access to physicians in rural areas, CMS is proposing to allow Rural Emergency Hospitals (REHs) to train residents and receive GME payments. Specifically, beginning on or after Oct. 1, 2023, an REH can include full-time equivalent (FTE) residents training at the REH in its direct GME and indirect medical education (IME) FTE counts for Medicare payment purposes. Alternatively, an REH can also incur direct GME costs and be paid based on reasonable costs for those training.

Trinity Health supports this policy.

Hospital Quality Reporting and Value Programs
Hospital Inpatient Quality Reporting (IQR) Program
Proposed in the regulation is the adoption, refinement, or removal of 23 measures. CMS is also updating the HCAHPS survey, and seeks comments on future inclusion of two geriatric care measures.

New eCQMs
Trinity Health supports the three proposed new eCQMs, as this information can be pulled easily from the EHR and the eCQMs outlined would be good for quality improvement. **In addition, we support refining the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure and the Hybrid Hospital-Wide All-Cause Readmission (HWR) measure to include Medicare Advantage patients**, as this is consistent with CMS goal of including this population in quality measures when there is the data to do so. **We caution CMS to continue to evaluate the quality of MA encounter data used for measures.**

HCAHPS Survey
In general, we support the changes outlined that would modernize the HCAHPS Survey. Specifically, we support adding web mail, web phone, and web-mail-phone as modes of survey administration. Many elderly patients require a proxy to respond/provide support for reporting of the HCAHPS survey, therefore Trinity Health appreciates CMS removing the requirement that only a patient may respond to the survey. In addition, limiting the number of survey items and requiring the use of official Spanish translation of the survey to patients who prefer Spanish will encourage patients to respond and improve data collection.

CMS seeks input on the potential addition of inclusion of patients with a primary psychiatric diagnosis in the survey. **Trinity Health already surveys psychiatric patients, albeit a little differently than the HCAHPS, and we'd support including this population in the HCAHPS survey as long as confidentiality and privacy is maintained.** We note that many of our patients with a primary psychiatric diagnosis are homeless and do not have access to email and this should be taken into account for any future policy. Prior to implementing such a policy, we recommend CMS outline how they will ensure parity. For example, if the psychiatric population is included in the HCAHP survey, do hospitals with these populations get compared to hospitals without?

Removal of two measures
CMS proposes to remove two measures from the IQR program that were adopted last year following substantive refinements to the measures: Hospital-Level Risk-Standardized Complication Rate Following Elective Primary

Total Hip Arthroplasty and/or Total Knee Arthroplasty Measure and Medicare Spending Per Beneficiary (MSPB)—Hospital Measure. Removal would be contingents on the revised measures being adopted into the Hospital VBP Program

We are concerned that publicly reported data could be confusing when displayed over time due to the measure definition changes. To the consumer, hospital performance would appear to worsen following measure definition changes for complications and MSPB. Trinity Health recommends CMS suppress one set of measure results from public reporting but maintain both results in the downloadable files.

Potential Future Geriatric Measure
CMS is considering future adoption of two attestation-based structural measures that would assess geriatric care across various domains. In addition, CMS is considering a geriatric care hospital designation to be publicly reported on a CMS website.

Trinity Health is supportive of including an attestation-based geriatric hospital measure and a geriatric surgical measure to assess geriatric care. If CMS moves forward with these measures, it will need to provide proactive outreach and education to providers on how to accurately collect and report data under this measure.

<u>COVID Vaccines for Health Care Personnel (HCP)</u>
Modified COVID-19 Vaccination Coverage among Health Care Personnel (HCP) Measure.
CMS adopted the COVID-19 Vaccination Coverage Among HCP measure across multiple quality reporting, including the Hospital IQR program, as part of FY22 rulemaking. CMS proses to modify the measure to align with CDC changes regarding whether an individual is considered "up to date' with COVID-19 vaccinations beginning in FY2025. Public reporting of the modified version of the measure would begin with the September 2024 Care Compare refresh or as soon as technically feasible.

Trinity Health is aware of recent action by CMS to withdraw the regulations in the interim final rule with comment (IFC) "Omnibus COVID-19 Health Care Staff Vaccination" published in the November 5, 2021 Federal Register, published on 6/5/2023. **For this proposed IPPS rule for federal FY24, we support adopting the CDC's definition of "up-to-date" for consistency but urge CMS transition from the current minimum of one week / month reporting of COVID-19 vaccination for healthcare personnel (HCP) to an annual, summary report. This would mirror that which CMS has and continues to require for influenza vaccination of HCP.** The weekly frequency of reporting consumes considerable resources by our member hospitals with little change of data between reporting quarters. An annual summary report will be sufficient to use data reported to continually improve protection of HCP against COVID-19.

In the rule, CMS notes that it does not believe updating the measure specifications will impose any additional burden on facilities and compares it to the annual influenza vaccination measure included in the Hospital IQR Program. **Trinity Health disagrees with CMS' assertion that the measure changes will not impose new burden on facilities.** If continued one week/month reporting is finalized, the measure will require ongoing tracking of adherence with periodically changing recommendations from CDC's Advisory Committee on Immunization Practices (ACIP). This is labor intensive and diverts use of resources from other work that is more pressing. As identified above, the current reporting of this measure is not similar to the annual influenza vaccination measure, which is a simple "yes" or "no" as to whether HCP have received their annual vaccination against influenza.

Further, we urge CMS collaborate with CDC's NHSN to be very clear about any final reporting requirement as the current requirement can be problematic from a technical standpoint if a provider picked a week in a month that crossed between two months. In this instance, reporting is not received by the CMS system and providers appear as non-compliant. Personnel entering data into NHSN under this situation are not aware that data entered is incomplete, i.e. the month in which the week began remains unreported. When the deadline for reporting the quarter in which this falls is passed the facility then unexpectedly discovers incomplete data which risks 25% APU incentive as well as loss of eligibility for other CMS performance improvement programs like Hospital Value-Based Purchasing (VBP). We recommend NHSN incorporate a real time alert to those entering this data indicating data entered is incomplete. The instructions from NHSN do include this limitation of NHSN however awareness of this and changes over time in personnel that oversee this reporting can result in missed opportunities for compliance with incentives from CMS.

While not identified in the current proposed IPPS rule for FY24, we recommend CMS communicate intent for coverage of provision of COVID-19 vaccine to patients admitted for inpatient care. Specifically, CMS should reimburse for the administration of vaccine as well as the cost of the dose of vaccine above the reimbursement of care for the reason for the patient's admission. This would also mirror current CMS policy for provision of pneumococcal and influenza vaccines during an inpatient admission and it is logical to extend this to COVID-19 vaccine now that the public health emergency (PHE) has ended.

Hospital Value Based Purchasing (HVP) Program

For HVP, CMS proposes to refine 2 measures, adopt one new measure, and implement a new health equity adjustment. Similar to the IQR program, CMS is proposing updates to HCAHPS and would codify measure retention and removal policies.

Trinity Health is concerned with the proposed measure Severe Sepsis and Septic Shock: Management Bundle and does not recommend CMS finalize the policy as it would continue to be incredibly burdensome for hospitals. It takes an average of 60 minutes to abstract one case and with current resources this is exceptionally challenging. Many of our hospitals outsource the abstractions due to limited resources, which is costly. **In addition, this measure is inconsistent with CMS' goal of replacing manually abstracted measures with electronic measures**. **Should CMS desire to move forward with incorporating a sepsis-specific quality measure into the Hospital Value-Based Purchasing Program in the future, we urge CMS to work with stakeholders to identify an outcome-based digital quality measure for sepsis.**

Trinity Health is conceptually supportive of the proposed equity adjustment that would reward hospitals that provide high quality care and serve a large proportion of vulnerable populations. However, there are potential concerns with the metrics for identifying underserved populations. There are several challenges with using dual eligibility and the other proxies that CMS is considering for measuring a hospital's underserved populations. For example, dual eligible beneficiary percentages will vary across states depending on nonuniform criteria for Medicaid eligibility. In addition, the Area Deprivation Index (ADI) may underreport underserved populations in high-cost geographies (recent Health Affairs article highlights this issue). Availability of ADI data can be limited for certain purposes (e.g., non-profit education, research and public health purposes) which may limit the ability of providers to partner with certain entities to ingest and validate data. **Trinity Health urges CMS to work with stakeholders to fine-tune the methodology for identifying underserved populations prior to adoption – especially in light of the redistributive impacts the addition of the bonus may have on Hospital VBP Program incentive payments.**

Clostridioides difficile CDC NHSN Health-Associated Infection (HA-CDI) Outcome Measure
Trinity Health does not support finalizing this measure until it receives NQF endorsement as wells as voluntary assessment of the value of the measure compared to existing hospital onset C. difficile infection (HO-CDI) measure. Further, collation of numerator and denominator will likely require more detailed review of patient EHR to extract these. There is a need to objectively evaluate this measure in terms of value it adds to not only internal trending but also inter-facility comparison.

CDC NHSN Hospital-Onset Bacteremia and Fungemia Outcome Measure
This measure captures the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in EHRs.

Trinity Health does not support proceeding with this measure under consideration until it receives NQF endorsement and there is a voluntary assessment of the value of this newly proposed measure. We also are concerned that hospital onset bacteremia and fungemia may be disproportionately more frequent at facilities that care for a higher proportion of immunocompromised patients. In addition, those cases who meet criteria for this measure will require considerable assessment for preventability. A notable proportion of hospital onset bacteremia and fungemia represent translocation of inherent microbial flora and we therefore question the preventability as compared to CLABSI. More voluntary investigation and testing of this measure is needed prior to widespread adoption.

Hospital Acquired Condition Reduction (HAC) Program
CMS seeks input on the adoption of new measures specifically on safety focused eCQMs, including measures focused on opioid related adverse events, severe hypoglycemia, severe hyperglycemia, acute kidney injury, and pressure injury. In addition, CMS is interested in measures that address emerging high priority patient harm events, equity gaps in the rate and severity of patient harm, and options for strengthening the program to encourage patient safety best practices.

Trinity Health is supportive of including the potential measures listed in the proposed rule. We also support best practices and have shared some of our work with AHRQ (also included in our response to the HHS patient safety RFI). We'd welcome the opportunity to help CMS develop the best practice measure. We urge CMS to also develop a safety measure focused on colleague safety and would welcome the opportunity to help develop this measure as well.

Promoting Interoperability Program (PIP)
CMS proposing For CY 2025 reporting period would be a minimum of any continuous 180 day period within CY2025. In addition, the rule would change how CMS considers reporting of the SAFER guides measures to require hospitals report "yes" in order to receive credit for the measure. Hospitals that report "no" for the SAFER measure would not be considered meaningful users.

Trinity Health supports a CY25 reporting period of 180 days; however, we do not recommend CMS extend the length of the reporting period beyond what is proposed until we can fully appreciate and understand operationally how 180 effects our reporting.

Regarding CMS's proposal to consider further extending the EHR reporting period, we ask that CMS consider impact of this on hospitals that, for example, transition EHRs during the calendar year OR hospitals that transition EHRs within 6 months of the start of the reporting period (as testing and validation of the new system would be active during this time). In addition, we request that CMS provide

clarification on the use of hardship exception in these situations – particularly when the EHR transition occurs within 6 months of the start of the reporting period since this may or may not be within the same calendar year. We ask CMS's consideration of this suggestion as a hospital's ability to meet PI Program requirements during a reporting period often requires additional investments into EHR systems. These investments can be costly and in situations when a hospital has made the decision to switch EHRs, investments into these legacy applications can be difficult to justify when the EHR transition is within the same budget year. Additional clarification from CMS regarding the use of hardship in this situation can significantly reduce a hospital's burden in making appropriate decisions regarding properly allocating resources while ensuring program compliance.

Request for Information: Safety Net Hospital

Trinity Health is committed to serving as a critical provider in our communities and coordinating care across settings and the care continuum. The settings in which we serve patients range from acute care to skilled nursing care, outpatient and clinic services, and community-based care in the home.

To maintain access to quality care for beneficiaries, reimbursement must cover the cost of delivering care. Unfortunately, payment rates to non-profit health systems such as Trinity Health have not kept up with the increased costs of delivering care across all settings.

The cost of caring for patients has increased significantly due to the extraordinary inflationary environment and continued labor and supply cost pressures. Since 2019, Trinity Health's cost per case has increased 14% including:

- 15% increase in labor costs.
- 17% increase in supply costs.
- 24% increase in drug costs.
- 10% increase in implant costs.

In addition, the average hospital length of stay has increased nationally by 19%[4]. Consequently, health systems are struggling to keep service lines open to care for our communities.

Because of their mission, safety net hospitals care for all people who cross their doors, regardless of ability to pay. In addition, hospitals are required to stabilize patients who show up at emergency rooms but are not required to treat them further, a wealthier, for-profit hospital can refuse the kind of community-oriented care that many safety nets provide. If a safety net closes, patients who are unable to pay could be left with nowhere to go.

A clear-cut definition for a safety net provider could help ensure targeted funding and should focus on key characteristics most safety nets share, including: the characteristics of the patients served, major sources of payments, community services provided, and how a hospital is investing in the community around it.

As it is highly likely that a new payment approach would redistribute funds currently available for hospitals, it is imperative that a safety net designation be data-driven, validated and reflect engagement by a wide range of stakeholders. This process should go beyond soliciting comments in a RFI or other rulemaking process and include stakeholder discussions that provide real-world context to data analysis and feedback received by CMS.

---

[4] Issue-Brief-Patients-and-Providers-Faced-with-Increasing-Delays-in-Timely-Discharges.pdf (aha.org)

These designations should also be informed by modeling results specific to individual health care organizations. Trinity Health would be happy to have further discussions and help CMS develop any future safety net policy.

How should safety-net hospitals be identified or defined?
Federal policy does not include a single definition of a safety net hospital. Instead, a range of special programs have been created to fund special categories of providers. Trinity Health does believe funding needs to be better targeted to hospitals that serve a disproportionate number of low income and vulnerable populations, including Medicare, Medicaid, and the uninsured.

A safety net provider should be defined as a provider for which at least 50% of their patients seen in the last year are enrolled in Medicaid and/or Medicare, or who are uninsured or rely on charity care. For Trinity Health, 59% of our revenue comes from Medicare, Medicaid and the uninsured.

In addition, Federally Qualified Health Centers and public hospitals should be included in any safety net definition.

Further, providers included in the definition should provide direct health care, including mental health and dental health whether it be through a stationary site or mobile services team that extends health care within an area containing disproportionate unmet health needs, including within a designated Medically Underserved Area or population. The definition should also include providers in ambulatory settings if they meet the outlined criteria.

We urge CMS to consider designating health systems who meet the above criteria as safety net providers.

As more care shifts to the ambulatory space, CMS should consider how to account for outpatient care provided by hospitals to underserved patients in a safety net hospital definition. Currently, an approach to quantify uncompensated care in an outpatient setting does not exist and would be useful to create as care shifts away from the inpatient setting.

To help better identify and define safety net hospitals, CMS can analyze data from the cost report worksheet S-10 for Medicaid and uncompensated care and cost reports for Medicare.

What factors should not be considered when identifying or defining a safety-net hospital and why?
It's important for any future policy to reflect safety net providers in both inpatient and outpatient settings. In addition, the geographic location of the provider should not preclude them from meeting the definition. Vulnerable populations live in all types of communities, although their circumstances may vary across urban, rural and suburban areas.

Targeting support to safety net providers is critical yet challenging given the variety of communities across the country, including differences in cost of living and population density. For example, there are safety net providers in urban areas that aren't captured when solely relying on certain indices, such as the Area Deprivation Index (ADI) (recent Health Affairs article highlights this issue). Any future definition or identifier of safety net provider must capture providers across settings geographies.

What are the main challenges facing safety-net hospitals?
As discussed above, reimbursement has not kept up with the cost of caring for patients and as a result it's harder for safety net providers to continue to meet the needs of their communities. In addition to challenges with

Medicare and Medicaid reimbursement, safety net providers are often not able to negotiate adequate payment from commercial payers because they do not have market dominance and have very little negotiating power. The result is that safety net providers tend to receive lesser rates from commercial insurers than non-safety net provides.

Safety net providers have patients with a disproportionate level of social needs, including food insecurity and homelessness. In addition, many patients who rely on safety net providers have challenges accessing transportation to receive care. Further, patients who receive services from safety net providers tend to have a higher acuity (ie. more chronic illness).

It is also challenging for safety net providers to attract qualified health care professionals and the cost of labor has increased significantly since 2019 (costs have increased 15% across Trinity Health). Further, these providers need more support to provide security and safety for staff and patients and for the technological updates necessary to improve care and maintain access to critical services.

What new approaches or modifications to existing approaches should be implemented or considered to address these challenges, either for safety-net hospitals in general, or for specific types of safety-net hospitals, including rural safety-net hospitals?
Safety net providers must be reimbursed fairly to cover the cost of caring for their patients. Given the current underpayment from all payers, CMS should ensure these providers receive additional funding in a consistent manner through an add on payment. Providing such funding through an add-on payment would make it easier to track by claim and would not require a settlement process that a lump sum payment or other arrangement would require. In addition, add on payment can directly flow through to Medicare Advantage claims. We also recommend CMS provide incentives in physician reimbursement schedules to help safety net providers recruit and retain providers.

Recognizing the critical role safety providers have in their communities, we recommend safety net providers be exempt from site neutrality policy similar to the protections afforded to sole community hospitals in last year's OPPS final regulation.

Many flexibilities provided during the COVID-19 PHE were exceptionally helpful for caring for vulnerable communities, including flexibilities for telehealth and supervision requirements. We urge CMS to work with stakeholders to identify targeted flexibilities that can be authorized for safety net providers and work with Congress, as needed, to implement.

Given the disproportionate need for social supports among patients who are served by safety net providers, HHS must provide funding to help these providers identify needs and connect patients to social care in their communities. Without strong connections to community services, safety net providers cannot adequately address the full needs of many individuals, which can lead to additional health challenges.

How helpful is it to have multiple types or definitions of safety-net hospitals that may be used for different purposes or to help address specific challenges?
Conceptually, Trinity Health would support a tiered approach of support based on the amount patients who are enrolled in Medicare and/or Medicaid, or who are uninsured or rely on charity care.

Are there specific payment approaches either as previously described or otherwise to consider for rural safety-net hospitals, including acute care hospitals and CAHs, to address challenges?
Recognizing the critical role safety providers have in their communities, we recommend safety net providers be exempt from site neutrality policy similar to the protections afforded to sole community hospitals in last year's OPPS final regulation. In addition, we recommend CMS provide incentives in physician reimbursement schedules to help safety net providers recruit and retain providers. It is crucial that CMS include outpatient services in designing safety net payments.

As one alternative, CMS could build from the existing DSH policy vehicle by analyzing the S-10 data. For example, CMS could assess the amount of uncompensated care provided by each hospital compared to the national total and then develop a methodology to provide a bump in payment for those providing relatively more uncompensated care. This approach has the benefit of administrative simplicity.

For any new or modified approaches, how can specific hospitals be identified as safety-net hospitals, or a type of safety-net hospital, using existing data sources? Are there new data sources that should be developed to better identify these hospitals?
We urge CMS to use existing data sources and not create a new layer of administrative burden to obtain data used to identify safety net providers.

To help better identify and define safety net hospitals, CMS can analyze S-10 data for Medicaid and uncompensated care and cost reports for Medicare. In addition, CMS can require a form 990 (schedule H) that outlines financial statements of non-profit providers that include the amount of charity care and community benefit provided. Whatever data sources are used, CMS should ensure public hospitals still qualify. Regardless of methodology used, it is crucial for CMS to have a transparent methodology that can be replicated by providers for their own planning purposes.

Is MedPAC's SNI an appropriate basis for identifying safety-net hospitals for Medicare purposes?
Over the years, policymakers have expressed concerns about the Medicare DSH and uncompensated care programs. Most recently, MedPAC has noted that the programs are:

- Poorly targeted to facilities that treat low-income Medicare beneficiaries
- Represent a cross-subsidy from Medicare to Medicaid due to the inclusion of Medicaid days in the formula
- Provide higher uncompensated care payments to hospitals with high Medicare Advantage shares (through the MA plans)
- Only accounts for inpatient care

MedPAC's SNI proposal is an attempt to better target safety net payments and it's possible it could result in additional funding for both inpatient and outpatient services to safety net providers. However, in order for Trinity Health to fully evaluate the proposal, MedPAC or CMS would need to release more granular data on the impacts of the redistributive policy across hospitals. To date, MedPAC has only released information on categories of hospitals. In addition, we need to know the specific formula that would be used to distribute the new SNI funds and how MedPAC determined the recommendation to add $2 billion to the SNI pool.

We have the following questions on the SNI proposal:

- The inclusion of guardrails during a transition period (such as a stop-loss or transition from DSH to SNI over a period of years) will be critical for hospitals that experience decreased safety-net payments under this policy. What transitional policies has MedPAC (or CMS) modeled?
- How will these payments flow through accountable care models? Has the impact on hospitals participating in value-based payment models been considered/modeled?

Lastly, in moving from DSH, which includes Medicaid days in the formula to the SNI, which includes only low-income Medicare beneficiaries (including duals), hospitals with high shares of Medicaid patients may lose funding under this program (note, this impact will be lower for hospitals with a high share of duals). Therefore, certain safety net hospitals could be harmed by the proposal. How would CMS recommend Congress and the states address the removal of a de facto cross-subsidy to Medicaid?

Should an area-level index, such as the ADI, be part of an appropriate basis for identifying safety-net hospitals?
While CMS does not specify how the ADI would be applied, Trinity Health has some general reservations about this use of an area-related index as well as the ADI itself. Specifically, we are concerned that an area-related index does not capture patient-specific situations, and thus its use as a proxy may not fully identify undeserved beneficiaries to whom hospitals are providing care. For example, if a patient had their own socioeconomic crisis in a more well-to-do area, it would not be identified through application of an area-related index. In fact, a similar limitation was recently identified in a Health Affairs article focused on the ADI,[5] which essentially noted that high home values can mask high deprivation in other social risk factors.

Are there social determinants data collected by hospitals that could be used to inform an approach to identify safety net hospitals? Are there HHS or CMS policies that could support that data collection?
Trinity Health recommends CMS use the Joint Commission Health Equity Standards and CMS Framework for Health Equity to support data collection of social determinants. Trinity Health is collecting social needs screening data and we've developed a working group to determining how to develop standard workflows to ensure robust hospital-based collections no later than January 2024. We also aggregate these data by race, ethnicity, gender, gender identity and could do sexual orientation as language preference.

What challenges do safety-net hospitals face around investments in information technology infrastructure?
Due to inadequate payment from all payers noted earlier in our comments and the vulnerable communities served by safety net providers, it is critical they receive funding for investments in technology for both inpatient and ambulatory care. Trinity Health recommends CMS provide an add on capital payment and work with stakeholders to determine the process and what data should be submitted.

Should safety-net hospitals' reporting burden and compensation be different than other hospitals? If so, how?
Safety net providers have fewer resources than other providers and serve a higher needs population. We encourage CMS to identify an equitable way of providing more funding to these providers and working with stakeholders to determine how to decrease their reporting burden while maintaining appropriate accountability.

---

[5] "ACO Benchmarks Based On Area Deprivation Index Mask Inequities", Health Affairs Forefront, February 17, 2023, https://www.healthaffairs.org/content/forefront/aco-benchmarks-based-area-deprivation-index-mask-inequities

What are the patient demographics at safety-net hospitals? What challenges do patients of safety net hospitals face before and after receiving care at the hospital?
Safety net hospitals have a mission to serve low-income, vulnerable populations, regardless of insurance coverage or ability to pay for services. As a result, these hospitals usually have high numbers of uninsured and Medicaid patients whose treatment costs aren't fully covered, which in turn means safety-net hospitals typically depend on public funding.

Safety net providers care for patients with a disproportionate level of social needs, including food insecurity and homelessness. In addition, many patients who rely on safety net providers have challenges accessing transportation to receive care. Further, patients who receive services from safety net providers tend to have a higher acuity (ie. more chronic illness). Patients who rely on these providers often have delayed diagnosis and care and may have complications from chronic conditions that are not adequately managed given limited access to care. In addition, it is hard to find placement for certain populations served, including those experiencing homelessness, after discharge and it is challenging to ensure patients receive follow-up care.

Given Administration efforts to reduce the patient burden of medical debt, are there ways to develop payment approaches for safety net hospitals that would also support hospital patients that need financial assistance?
The most critical thing that can be done is to ensure safety net providers are reimbursed fairly for the cost of caring for patients. Today, payment does not cover the cost of caring for patients, which has increased significantly due to the extraordinary inflationary environment and continued labor and supply cost pressures. Since 2019, Trinity Health's cost per case has increased 14% including:

- 15% increase in labor costs.
- 17% increase in supply costs.
- 24% increase in drug costs.
- 10% increase in implant costs.

Trinity Health has a generous financial assistance policy and presumptive charity policy and encourages all safety net providers to develop similar policies. In addition, CMS should help qualifying individuals meet their financial obligations (ie. expand QMB/SLMB).

Conclusion
We appreciate CMS's ongoing efforts to improve payment systems across the delivery system. We welcome the opportunity to inform any future safety net policy and would be happy to partner with CMS. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health